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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,450	02/27/2004	Grzegorz Bulaj	2699-5613.1US	8779

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EXAMINER

GEBREYESUS, KAGNEW H

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 10/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/789,450

Applicant(s)

BULAJ ET AL.

Examiner

Kagnew H Gebreyesus

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-27 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-10 are drawn to DNA, host cells and expression of protein disulfide isomerase of SEQ ID NO: 1, classified in class 536, subclass 23.2.
 - II. Claims 1-10 are drawn to DNA, host cells and expression of protein disulfide isomerase of SEQ ID NO: 3, classified in class 536, subclass 23.2.
 - III. Claims 1-10 are drawn to DNA, host cells and expression of protein disulfide isomerase of SEQ ID NO: 5, classified in class 536, subclass 23.2.
 - IV. Claims 1-10 are drawn to DNA, host cells and expression of protein disulfide isomerase of SEQ ID NO: 7, classified in class 536, subclass 23.2.
 - V. Claims 17 is drawn to protein disulfide isomerase of SEQ ID NO: 2, classified in class 435, subclass 233.
 - VI. Claims 17 is drawn to protein disulfide isomerase of SEQ ID NO: 4, classified in class 435, subclass 233.
 - VII. Claims 17 is drawn to protein disulfide isomerase of SEQ ID NO: 6, classified in class 435, subclass 233.
 - VIII. Claims 17 is drawn to protein disulfide isomerase of SEQ ID NO: 8, classified in class 435, subclass 233.

- IX. Claims 11-16 are drawn to an in vivo cell culture method of producing a correctly folded disulfide rich peptide, in any one of the following host cells; insect cells, HIGH FIVE, Sf9, Sf21, Drosophila Schneider2, a mammalian cell, COS 1, NIH 3T3, HeLa, 293, CHO, U266, Plant cells, Baculovirus, Saccharomyces, Schizosaccharomyces, Aspergillus, E. coli and Bacillus using a disulfide isomerase of SEQ ID NO: 2, classified in class 435, subclass 69.1.
- X. Claims 11-16 are drawn to an in vivo cell culture method of producing a correctly folded disulfide rich peptide, in any one of the following host cells; insect cells, HIGH FIVE, Sf9, Sf21, Drosophila Schneider2, a mammalian cell, COS 1, NIH 3T3, HeLa, 293, CHO, U266, Plant cells, Baculovirus, Saccharomyces, Schizosaccharomyces, Aspergillus, E. coli and Bacillus using a disulfide isomerase of SEQ ID NO: 4, classified in class 435, subclass 69.1.
- XI. Claims 11-16 are drawn to an in vivo cell culture method of producing a correctly folded disulfide rich peptide, in any one of the following host cells; insect cells, HIGH FIVE, Sf9, Sf21, Drosophila Schneider2, a mammalian cell, COS 1, NIH 3T3, HeLa, 293, CHO, U266, Plant cells, Baculovirus, Saccharomyces, Schizosaccharomyces, Aspergillus, E. coli and Bacillus using a disulfide isomerase of SEQ ID NO: 6, classified in class 435, subclass 69.1.
- XII. Claims 11-16 are drawn to an in vivo cell culture method of producing a correctly folded disulfide rich peptide, in any one of the following host cells; insect cells, HIGH FIVE, Sf9, Sf21, Drosophila Schneider2, a mammalian cell, COS 1, NIH 3T3, HeLa, 293, CHO, U266, Plant cells, Baculovirus, Saccharomyces,

Schizosaccharomyces, Aspergillus, E. coli and Bacillus using a disulfide isomerase of SEQ ID NO: 8, classified in class 435, subclass 69.1.

- XIII. Claims 18-27 are drawn to an in vitro transcription/translation method of producing a correctly folded disulfide rich peptide using protein disulfide isomerase selected from the group as set forth in SEQ ID NO: 2, a protein having 57% identity to said protein disulfide isomerase and a fragment thereof with disulfide isomerase activity classified in class 435, subclass 68.1.
- XIV. Claims 18-27 are drawn to an in vitro transcription/translation method of producing a correctly folded disulfide rich peptide using protein disulfide isomerase selected from the group as set forth in SEQ ID NO: 4 a protein having 57% identity to said protein disulfide isomerase and a fragment thereof with disulfide isomerase activity classified in class 435, subclass 68.1.
- XV. Claims 18-27 are drawn to an in vitro transcription/translation method of producing a correctly folded disulfide rich peptide using protein disulfide isomerase selected from the group as set forth in SEQ ID NO: 6 a protein having 57% identity to said protein disulfide isomerase and a fragment thereof with disulfide isomerase activity classified in class 435, subclass 68.1.
- XVI. Claims 18-27 are drawn to an in vitro transcription/translation method of producing a correctly folded disulfide rich peptide using protein disulfide isomerase selected from the group as set forth in SEQ ID NO: 8 a protein having 57% identity to said protein disulfide isomerase and a fragment thereof with disulfide isomerase activity classified in class 435, subclass 68.1.

1. The DNA of Group I-IV and the protein of Group II-VIII each comprise a chemically unrelated structure capable of separate manufacture, use and effect. The DNA of Group I-IV comprise nucleic acid sequences and the proteins of group II comprise unrelated amino acid sequences. The DNA has other utilities besides encoding the protein such as hybridization probe, the proteins can be made by another method such as isolation from natural sources or chemical synthesis and the proteins have other utilities besides acting as catalysts such as antigens for the induction of antibodies used in detection and purification methods.

2. Inventions In Groups I-IV and inventions in Groups IX-XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the nucleic acid molecules of Groups I-IV are not used in the method of making correctly folded disulfide rich polypeptides.

3. Inventions in Groups IV-VIII and in Groups IX-XVI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the disulfide isomerases of Group IX-XVI can induce the production of antibodies that in turn can be used in detection and/or affinity purification of the disulfide isomerase itself.

4. Although there are no provisions under the section for "Relationship of Inventions" in the MPEP § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper between the methods of Group IX-XII and the method Group XIII-XVI because of

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the following reasons: Group IX-XII and the method Group XIII-XVI recite structurally and functionally different elements, are not required one for the other. Invention in Group IX-XII requires transforming a microorganism with a recombinant gene while the methods of Group XII-XVI do not require the steps of transformation with a recombinant vector expressing the gene. Therefore the in vivo cell culture methods of Group IX-XII and the in vitro transcription translation method Group XIII-XVI are independent as they comprise different steps and/or utilize different products.

5. The four different nucleic acid sequence of Groups I-IV (SEQ IDNO: 1, 3, 5, 7 encode four different types of disulfide isomerases of Group V-VIII, however each of the nucleic acid sequence of Group I-IV has a different structure and encodes the four different proteins protein disulfide isomerases of Groups V-VIII which may catalyze the folding of different group of disulfide rich proteins from different sources in addition to the large number of disulfide rich proteins in the venom of the Conus snails. Therefore each of the inventions in Group I-IV and each of the inventions in Group V-VIII are related but and patentably distinct. Because these inventions are distinct for the reasons given above restriction for examination purposes as indicated is proper.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.43).

8. Applicant is reminded that upon the cancellation of claims to a none elected invention the none elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48 (b) and by the fee required under 37 CFR 1.17 (i).

9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

10. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined.

See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re*


Brouwer and 35 U.S.C. § 103(b),” 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kagne H Gebreyesus whose telephone number is 571-272-2937. The examiner can normally be reached on 8:30am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Achutamurthy Ponnathapura can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kagne H Gebreyesus Ph.D.
AU 1652


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PRIMARY EXAMINER
GROUP 1800
1/10/07